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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/622,762 | 07/20/2003 | Weihua Zhang | P-SP001 | 2459 |

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| EXAMINER |
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BOWERS, NATHAN ANDREW

| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,762

Applicant(s)

ZHANG ET AL.

Examiner

Nathan A. Bowers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 1) Claims 1-3, 6, 8-11, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by McCormick (US 3745091).

With respect to claims 1 and 20, McCormick discloses a cell culture system comprising a cell culture container partitioned into two or more compartments by a rectangular removable unit (Figure 1:14). The bottom edge of the removable partition unit is in contact with the base (Figure 1:12) of the cell culture container. The removable partition unit can be lifted off of the base at any time during experimentation. This is disclosed in column 1, lines 11-26, column 2, lines 1-58, and column 3, lines 59-61. Since McCormick's invention is directed to cell culturing procedures, it is capable of being used to culture different types of cells in each of the various compartments. Furthermore, McCormick's apparatus is also capable of being used to monitor cell migration between compartments once the partition unit is removed. These limitations merely represent intended uses of the device (See MPEP 2114).

With respect to claim 2, McCormick discloses the apparatus in claim 1 wherein the base of the cell culture container is considered to either be a culture dish or a culture chamber slide.

With respect to claim 3, McCormick discloses the apparatus in claim 1 wherein the base of the cell culture container is made from an organoplastic. This is disclosed in column 2, lines 43-58. In column 3, lines 11-13, McCormick indicates that transparent polystyrenes are known in the art as useful materials.

With respect to claim 6, McCormick discloses the apparatus in claim 1 wherein the removable partition unit is made from polystyrene. This is disclosed in column 3, lines 11-13.

With respect to claim 8, McCormick discloses the apparatus in claim 1 wherein the bottom edges of the removable portion unit are in straight line configurations. This is apparent from Figure 2.

With respect to claims 9-11, McCormick discloses the apparatus in claim 1 wherein the bottom edge of the removable portion is attached and sealed onto the cell culture surface of the cell culture container by sealing glue. Column 3, line 41 to column 4, line 11 discloses the use of an adhesive gasket (Figure 3:48) as a means by which to connect the base to the removable portion. McCormick states that "the receptacle can be easily removed form the base by pulling it away from the base," and that the adhesive gasket is "non-toxic to the biological material subsequently employed in the apparatus, and does not act as a source of growth for microorganisms." Furthermore,

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McCormick indicates that the adhesive gasket is an organopolysiloxane elastomer, which is a type of silicone glue.

With respect to claim 23, McCormick discloses the apparatus in claim 20 wherein the rectangular area is further divided into addition compartments by the removable partition unit. This is apparent from the Figures.

2) Claims 1-4, 8, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters (US 4299920).

With respect to claims 1 and 20, Peters discloses a cell culture container (Figure 2:3) partitioned into two or more compartments by a rectangular removable partition unit (Figure 2:1). The bottom edge of the removable partition unit is in contact with the cell culture surface of the culture container. This is disclosed in column 1, lines 5-11 and lines 36-55.

With respect to claim 2, Peters discloses the apparatus in claim 1 wherein the culture container is considered to be either a culture dish or a culture chamber slide.

With respect to claim 3, Peters discloses the apparatus in claim 1 wherein the culture container is made from either glass or polystyrene. This is disclosed in column 2, lines 27-36.

With respect to claim 4, Peters discloses the apparatus in claim 1 wherein the culture container is treated or coated with biomembranes and biomolecules for the culture of specific cell types. This is disclosed in column 3, lines 14-32.

With respect to claim 8, Peters discloses the apparatus in claim 1 wherein the bottom edges of the removable portion unit are in straight line configurations. This is apparent from the Figures.

With respect to claim 23, Peters discloses the apparatus in claim 20 wherein the rectangular area is further divided into addition compartments by the removable partition unit. This is apparent from the Figures.

3) Claims 1-10, 20-23, 28 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim (US 20030036188).

With respect to claims 1, 28 and 33, Kim discloses a cell co-culture system comprising a cell culture container (Figure 1:140) partitioned into two or more compartments by a removable partition unit (Figure 1:150) in such a way that the bottom edge of the removable partition is in contact with the cell culture surface. This is disclosed in paragraphs [0059]-[0070]. Paragraphs [0200]-[0209] clearly indicate that different types of cells can be cultured in each of the compartments, and that cellular interaction/migration is observed in an area on the cell culture container covered by the bottom edge of the removable partition after the removal of said partition unit.

With respect to claims 2, 3 and 6, Kim discloses the apparatus in claim 1 wherein the cell culture container is considered to be either a culture dish or a culture chamber slide. The cell culture container is made from polystyrene, glass, or plastics, and the removable partition unit is made from glass. This is disclosed in paragraph [0034].

With respect to claim 4, Kim discloses the apparatus in claim 1 wherein the cell culture container is treated/coated with biomolecules for the culture of a specific cell type. Paragraphs [0045], [0158] and [0210] teach that the upper surface of the culture container is treated with a variety of coatings.

With respect to claims 5, 7 and 22, Kim discloses the apparatus in claims 1 and 20 wherein the cell culture container is a rectangle with a length of 75 mm and a width of 125 mm. Therefore, the diagonal dimension of the cell culture container must be 146 mm. This is disclosed in paragraph [0135]. Furthermore, Kim gives additional specifications in paragraph [0141] that indicates that the width of the area covered by the bottom surface of the removable partition unit on the cell culture container is from 0.01 to 10 mm. For instance, if the diameter “d” of the microwell (Figure 4:300) is 5 mm and the distance “p” between the microwells is 2 times the diameter “d”, then the width of the bottom surface of the removable partition between the microwells must be 5 mm.

With respect to claim 8, Kim discloses the apparatus in claim 1 wherein the bottom edges of the removable portion unit are in straight line configurations. This is apparent from the Figures.

With respect to claims 9 and 10, Kim discloses the apparatus in claim 1 wherein the bottom edge of the removable partition unit is attached and sealed onto the culture surface of the cell culture container using a sealing glue. This is disclosed in paragraph [0157].

With respect to claims 20 and 23, Kim discloses the apparatus in claim 1 wherein the removable partition unit is rectangular in shape and encloses a plurality of

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rectangular areas on the cell culture container. This is disclosed in paragraph [0139] and in the Figures.

With respect to claim 21, Kim discloses the apparatus in claim 20 wherein the removable partition unit is attached to the cell culture surface by direct and tight contact between optically polished surfaces of the partition unit and the cell culture container. Furthermore, the removable partition unit further comprises holders (Figure 3:190) that secure the position of the partition unit on the cell culture container. This is disclosed in paragraph [0186]. Paragraph [0157] additionally discloses the use of other mechanical sealing devices such as clamps.

4) Claims 1-3, 6, 8, 16, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Morozov (US 5952191).

With respect to claims 1, 16, 17 and 20, Morozov discloses a cell culture system comprising a cell culture container partitioned into two or more compartments a removable unit (Figure 3:6). The bottom edge of the removable rectangular partition unit is in contact with the base (Figure 3:4) of the cell culture container. Approximate cylindrical partition units are disclosed in Figures 10 and 11. The removable partition unit can be lifted off of the base at any time during experimentation. This is disclosed in column 5, line 64 to column 6, line 44. Since Morozov's invention is directed to cell culturing procedures, it is capable of being used to culture different types of cells in each of the various compartments. Furthermore, Morozov's apparatus is capable of being used to monitor cell migration between compartments once the partition unit is

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removed. These limitations merely represent intended uses of the device (See MPEP 2114).

With respect to claims 2, 3 and 6, Morozov discloses the apparatus in claim 1 wherein the cell culture container is a cell culture dish. The culture container and the removable portion are both constructed from either polystyrene or glass. This is taught in column 8, lines 1-7.

With respect to claim 8, Morozov discloses the apparatus in claim 1 wherein the bottom edges of the removable portion unit are in straight line configurations. This is apparent from the Figures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5) Claims 16-19 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (US 20030036188).

With respect to claims 16-19, Kim discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. Kim teaches that a plurality of circular areas on the cell culture container are enclosed by the removable partition unit. Kim, however, does not expressly disclose that the removable partition unit itself is cylindrical in shape. Regardless, it is believed that the claims are still unpatentable over Kim because changes in the shape of the removable portion do not change the function of the device in an unexpected manner. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966), the Federal Circuit held that a claimed device is not patentably distinct from the prior art based on the simple recitation of relative dimensions. Accordingly, the claimed dimensions and shapes are

considered to be not patentably distinct from the disclosed Kim device (See MPEP 2144.04 IV).

With respect to claim 34, Kim discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. In addition, Kim discloses a method for using the device in which different types of cells are cultured in each of the compartments. The removable partition is later withdrawn in order to monitor the movement of cells in the co-culture system. Kim, however, does not expressly disclose that the bottom edge of the removable partition unit comprises a sawtooth-shaped configuration. Regardless, it is believed that the claim is still unpatentable over Kim because changes in the shape of the bottom edge of the removable portion do not change the function of the device in an unexpected manner. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966), the Federal Circuit held that a claimed device is not patentably distinct from the prior art based on the simple recitation of relative dimensions. Accordingly, the claimed dimensions and shapes are considered to be not patentably distinct from the disclosed Kim device (See MPEP 2144.04 IV).

6) Claims 12-15, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (US 20030036188) as applied to claim 1, and further in view of Morozov (US 5952191).

With respect to claims 12-15, Kim discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. In paragraph [0157], Kim additionally teaches the use of sealing materials to attach the partition unit to the cell culture surface. Silicon glue and rubber sealing materials are considered to be well known in the art. Kim, however, does disclose a central culturing cylinder located in the middle of the cell culture dish. Kim does not indicate that removable partition units are connected to the walls of the culture dish and to the central culturing cylinder.

Morozov discloses the apparatus as previously described. In Figure 6, Morozov discloses an embodiment in which a central culturing area is located in the middle of the cell culture dish. A plurality of removable partition units are attached to the central culturing area and the walls of the cell culture dish, however the central culturing area is not cylindrical. Figure 10 illustrates a similar embodiment in which the central area is more cylindrical in shape. In column 7, lines 21-25, Morozov indicates that the removable partition unit ends make tight contact with the vertical walls of the dish.

Kim and Morozov are analogous art because they are from the same field of endeavor regarding cell co-culture apparatuses with partitions.

At the time of the invention, it would have been obvious to alter the construction of Kim's removable partition unit in order to create a central culturing cylinder with radially extending partition dividers connected to the central culturing cylinder and the walls of the cell culture dish. In column 7, lines 15-20, Morozov indicates that this configuration is advantageous because it provides a plurality of sample areas surrounding the central culturing area that are equal in size, and equal in distance away

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from the central culturing area. This would be beneficial when applied to Kim's apparatus in method because it would ensure that all surrounding regions are identical during cell movement from the central area after the removal of the partition. Furthermore, it would have been desirable to ensure that the edges of the partition walls radiating from the central area are attached to the culture dish walls, especially since Kim discloses the use of sealing materials in paragraph [0157]. This would guarantee that cells are not given a chance to migrate between enclosed areas before the partition is removed.

With respect to claims 30 and 31, Kim and Morozov disclose the apparatus set forth in claim 12 as set forth in the 35 U.S.C. 103 rejection above. In addition, Kim discloses a corresponding method in which different types of cells are cultured in the different compartments. The partition unit is then removed, and cell-cell interactions are examined as cells move from their compartments and into the areas previously covered by the bottom edge of the removable partition unit.

7) Claims 24, 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (US 20030036188) as applied to claims 1 and 28, and further in view of Frost (US 3485236).

Kim discloses the apparatus and method set forth in claims 1 and 28 as set forth in the 35 U.S.C. 102 rejections above, however does not disclose a corresponding cell sampler.

Frost discloses a cell sampler that comprises a cutting portion (Figure 5:18) with a protruding edge (Figure 5:26) on one end of the device, and a sampling portion (Figure 5:20) on the opposite end of the device. This is disclosed in column 2, line 43 to column 3, line 25. From the Figures, it is clear that the cutting and sampling ends are generally rectangular in shape. Although Frost does not clearly disclose the specific sizes of the cutting and sampling ends, it would have been obvious to construct the cutting and sampling ends to meet the claimed limitations. Varying the geometry of the device to achieve the most favorable design is simply the optimization of result effective variables that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the sampling end has a diameter from 5 to 50 mm. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and MPEP 2144.05.

Kim and Frost are analogous art because they are from the same field of endeavor regarding cell culturing devices.

At the time of the invention, it would have been obvious to manipulate the cells growing and migrating on Kim's device using a cell sampler similar to the one disclosed by Frost. Frost indicates that multi-functional cell samplers comprising two oppositely arranged manipulating ends are well known in the art. The protruding edge of the cutting portion is intrinsically capable of cutting around a cell sample of interest in an effort to isolate it from the other colonies. The rectangular end of the sampling portion is intrinsically capable of scooping up the isolated cell sample and transporting it to another location for further analysis.

8) Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (US 20030036188) in view of Morozov (US 5952191) as applied to claim 30, and further in view of Frost (US 3485236).

Kim and Morozov disclose the method set forth in claim 30 as set forth in the 35 U.S.C. 103 rejection above, however do not disclose the use of a corresponding cell sampler.

Frost discloses a cell sampler that comprises a cutting portion (Figure 5:18) with a protruding edge (Figure 5:26) on one end of the device, and a sampling portion (Figure 5:20) on the opposite end of the device. This is disclosed in column 2, line 43 to column 3, line 25.

Kim, Morozov and Frost are analogous art because they are from the same field of endeavor regarding cell culturing devices.

At the time of the invention, it would have been obvious to manipulate the cells growing and migrating on Kim and Morozov's device using a cell sampler similar to the one disclosed by Frost. Frost indicates that multi-functional cell samplers comprising two oppositely arranged manipulating ends are well known in the art. The protruding edge of the cutting portion is intrinsically capable of cutting around a cell sample of interest in an effort to isolate it from the other colonies. The rectangular end of the sampling portion is intrinsically capable of scooping up the isolated cell sample and transporting it to another location for further analysis.

9) Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (US 20030036188) in view of Frost (US 3485236) as applied to claim 24, and further in view of Altshuler (US 5259391).

Kim and Frost disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use polycarbonate membranes on the cell sampling surface.

Altshuler discloses a cell sampler that comprises a cell sampling surface (Figure 1:1). Column 2, line 62 to column 3, line 21 and column 3, line 58 to column 4, line 20 teach that the cell sampling surface is provided with a polycarbonate membrane to facilitate the transfer of cells.

Kim, Frost and Altshuler are analogous art because they are from the same field of endeavor regarding cell culturing instruments.

At the time of the invention, it would have been obvious to provide the sampling end of the cell collection device disclosed by Frost with a polycarbonate membrane. Altshuler teaches in column 3, lines 7-10 that polycarbonate membranes are beneficial because they can be removed from the cell sampler after cells have been collected. This allows the cells to be more easily observed under a microscope and incorporated into other types of sample processing devices.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Pugh (US 5861306), Turner (US 5571721), Sforza (US

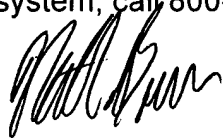
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4053362), Marotzki (US 6468788) and Haque (US 4042463) references disclose the state of the art regarding cell culture devices comprising partitions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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